

Product Specification

Meets B.P. Chemical Specifications, Meets N.F. Requirements, Meets J.P. Chemical Specifications, Meets E.P. Chemical Specifications, GMP Manufactured Product

| Test | Specification |
|---|----------------|
| NF – Assay (C ₁₀ H ₁₂ O ₃) | 98,0 – 102,0 % |
| NF – Identification A | Passes Test |
| NF – Identification B | Passes Test |
| NF – Color of Solution | Passes Test |
| NF – Acidity | Passes Test |
| NF – Related Substances – p-Hydroxybenzo | ≤ 0,5 % |
| NF – Related Substances – Unspecified Im | ≤ 0,5 % |
| NF – Related Substances – Total Impuriti | ≤ 1,0 % |
| NF – Residue on Ignition | ≤ 0,1 % |
| EP/BP – Assay (C ₁₀ H ₁₂ O ₃) | 98,0 – 102,0 % |
| EP/BP – Appearance of Solution | Passes Test |
| EP/BP – Identification A | Passes Test |
| EP/BP – Identification B | Passes Test |
| EP/BP – Acidity | Passes Test |
| EP/BP – Related Substances – Impurity A | ≤ 0,5 % |
| EP/BP – Related Substances – Unspecified | ≤ 0,5 % |
| EP/BP – Related Substances – Total Impur | ≤ 1,0 % |
| EP/BP – Sulfated Ash | ≤ 0,1 % |
| JP – Assay | 98,0 – 102,0 |
| JP – Identification | Passes Test |
| JP – Melting Point | 96 – 99 °C |
| JP – Acidity | Passes Test |
| JP – Clarity and Color of Solution | Passes Test |
| JP – Heavy Metals | ≤ 20 ppm |
| JP-RelatedSubstances– p-Hydroxybenzoic A | ≤ 0,5 % |
| JP-Related Substances–Unspecified Impuri | ≤ 0,5 % |
| JP-Related Substances–Total Impurities | ≤ 1,0 % |
| JP – Residue on Ignition | ≤ 0,10 % |

Propylparaben
NF – GenAR®



Material No.: 7624-06

Test

Specification

GMP Manufactured Product

Bulk Pharmaceutical Chemical

CAUTION: For Manufacturing, processing or repackaging

Only the Class 3 solvent 1-propanol is present. The concentration is controlled below 0.5%.

Elemental Impurities (USP 232, EP 5.20) – Information on elemental impurities for this product is available on the associated Product Regulatory Data Sheet and elemental impurity profile report.

Storage Condition: Store in a tightly closed container.

Packaging Site: Paris Mfg Ctr & DC

Jamie Ethier
Vice President Global Quality

For questions on this Product Specification please contact Technical Services at 855.282.6867 or +1.610.386.1700

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